

AMENDMENT
1-15368REMARKSCLAIM REJECTIONS35 USC § 102

The Examiner has stated in paragraph two of the detailed action that "Claims 32-43 are rejected under 35 USC § 102(b) as being anticipated by Bartels, et al. (US 4,621,632)". The rejection of claims 32-43 as being anticipated by Bartels, et al. is in error and must be withdrawn. For an anticipation rejection to be proper, everything in the claim recited by the Examiner must be within the "four corners" of the cited reference. Since the claim under consideration is a method claim, this means that every step of applicant's method must be shown in Bartels, et al. Among the steps which the Examiner says are shown by Bartels is "sensing the humidity of the gas as it exits the chamber and monitoring the humidity of the gas exiting the chamber". Bartels simply does not perform these steps.

Referring to Figures 1-3 of Bartels, and column 8-9 of the patent, it can be seen that Bartels has a humidification chamber 8, having an air inlet port 32, and an air outlet port 34, which fits over a heater assembly 54. A water reservoir 50 is formed in the tapered base portion 31 of the humidifier chamber 8, and water is admitted to the reservoir from delivery tube 20. The air inlet port 32 is connected to a ventilator, while the air outlet port 34 supplies gas to the patient through the flexible heating tube 36, which may have an optional heater element 42. The inside of the humidifier chamber 8 has a cylindrical shroud portion 30, which has a spiral heat exchange surface 56 forming a path in the center of the chamber, approximate the air inlet port 32, and going to the outside of the chamber proximate the air outlet port 34. Humidified air is supplied from the base portion 31, to the center of the shroud portion 30. As stated at column 8, line 51, "During that portion of the patients breathing cycle referred to as exhalation, a supply of vapor is deposited in the vapor storage chamber 58 of the humidifier chamber shroud portion 30. The air at storage chamber 58 is overheated and over humidified (beyond the pre-determined set points), so as to cause a thin layer of water to form around the surface of chamber 58. Excess water is

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drained, by means of gravity, from vapor storage 58 to the water return reservoir 52 (of FIG. 2) of base portion 31 where it may be re-boiled and re-vaporized.

During that portion of the patients breathing cycle referred to as inspiration (i.e., when incoming air supplied to the air inlet port 32 of shroud portion 30 by a ventilator), air is pumped through the gap 62 of vapor storage chamber 58, where it acquires an excess of vapor. The vapor saturated air is then supplied to the distal end of the spiral heat exchange contact surface 56 of shroud portion 30. Hence, water will rain out (condense) from the vapor saturated air as it traverses the spiral path of the continuous and relatively cooler heat exchange surface 56, so as to assure 100% relative humidity."

Therefore, the Bartels device is designed to assure, at the start of inspiration, because of the rain out, a 100% relative humidity at air outlet port 34. As long as the temperature at air outlet port 34 remains constant through the travel of the air, through the flexible heating tube 36, Bartels is assured of 100% relative humidity at a particular temperature. However, there is no monitoring of humidity, nor any sensing of humidity. Referring to column 9, lines 32-43, it is stated that "In the event that insufficient vapor remains in the shroud portion 30 after inspiration is completed, the end of the patients breath will be characterized by relatively low temperature and humidity. However, the outgoing air can be conditioned during the patient's next breath to achieve the desired temperature (35°C.) and relative humidity (100%) in a manner and by means of the humidifier system control circuitry which is now disclosed in detail... in Figures 1-8 of the drawings."

Bartels et al. concedes that he doesn't know what the actual humidity is during the patient's breath. There are no alarms that go off, and nothing to tell him whether it is still at 100% or not. Thus, the steps of monitoring humidity and sensing humidity are not within the four corners of the Bartels reference. Therefore, the Examiner's rejection under 35 U.S.C. § 102 is improper and claims 32-43 are allowable.

It should be pointed out that the audible warning of Bartels et al. is for temperature only. The description at column 12, lines 9-15 confirms this. It is stated "the control micro-processor

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unit 106 is electrically interconnected with analog to digital converter 98 so as to enable converter 98 (via an output line designated START) and to receive information (via an input line designated CONVERT) from which the proximal temperature of the humidified air being delivered to the patient can be sensed and subsequently adjusted. It is not an audible warning for a specific level of relative humidity. It is not relative a humidity sensor, nor is it acting like one. The present invention is specifically devised to give an audible warning at a preset relative humidity. It has a sensor that gives an audible warning when a low level of relative humidity is reached.

35 USC § 103

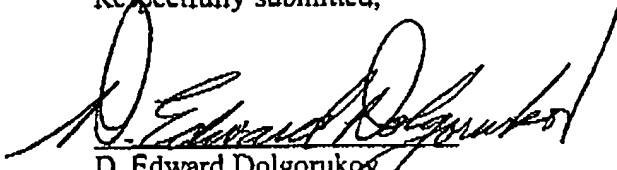
The Examiner also rejects claim 44 as being obvious in view of the combination of Bartels et al., in view of Ott, et al (5,411,474). The Examiner states "Bartels et al. teaches all of the limitations of the claim except for filtering the gas prior to the step of humidifying. Ott, et al. teaches that "it is known to filter insufflation gas" to prevent passing of inorganic molecules. The location and type of filter, however, are very important factors which will influence the effectiveness of the method. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to have modified the insufflation device taught by Bartels et al. with the placement of a filter as taught by the insufflation device of Ott, et al. for the purpose of preventing inorganic molecules from reaching the respiratory system." It is respectfully pointed out, as set forth above, that Bartels et al. does not teach all of the limitations of the claims, except for filtering the gas prior to the step of humidifying. Specifically, the steps of sensing the humidity of the gas as it exits the chamber and monitoring the humidity of the gas exiting the chamber are not shown by Bartels et al. Therefore, the combination proposed by the Examiner does not make obvious the method defined in claim 44.

The Amendment of claim 38 is being made for the purpose of clarity only, and not for the purposes of patentability. Claim 38 depends on an allowable parent claim and therefore would be allowable in its present form. The claim has simply been amended to be consistent with the specification.

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Therefore, in view of the above amendments, and the remarks explanatory thereof, a favorable reconsideration of the present application, and the passing of this case to issue is courteously solicited. If for any reason the Examiner finds that the case is not in an allowable condition, a telephone interview is courteously requested.

Respectfully submitted,


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